IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

:

UNITED STATES OF AMERICA

CRIMINAL NO:

20-CR-00200-RBS

v.

DATE FILED:

TEVA PHARMACEUTICALS

VIOLATION:

USA, INC. and

15 U.S.C. § 1

GLENMARK

(conspiracy in restraint of

PHARMACEUTICALS INC.,

trade - 3 counts)

USA

.

SECOND SUPERSEDING INDICTMENT

COUNT ONE CONSPIRACY TO RESTRAIN TRADE (15 U.S.C. § 1)

THE GRAND JURY CHARGES THAT:

At all times relevant to this count:

BACKGROUND

- 1. A generic drug is a medication created to be the same as an existing approved brand name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics. Most generic drugs are known by the name of their active ingredient.
- 2. The generic version of a drug is less expensive to purchase than its brand name equivalent. For this reason, state laws often require pharmacists to fill prescriptions for a particular drug with its generic rather than its brand name version. Nearly 90% of all prescriptions in the United States are filled with generic drugs.

- 3. Companies that sell generic drugs may manufacture those drugs in their own facilities or purchase them from others (collectively referred to as "manufacturers").

 Manufacturers usually sell their generic drugs to a number of different types of customers, including wholesalers, distributors, retail drug stores, drug store chains, and group purchasing organizations.
- 4. Manufacturers of generic drugs are required by federal regulation to identify a price known as the "Wholesale Acquisition Cost," or "WAC," for each drug they sell. The WAC is defined as the manufacturer's list price to wholesalers or direct purchasers for the most recent month for which information is available. It does not represent actual transaction prices and does not include discounts or rebates. Manufacturers generally announce a new WAC by notifying their customers in writing. Such announcements are typically reported promptly in one or more commercial publications that are available to both customers and manufacturers in the pharmaceutical industry.
- 5. Customers often enter into contracts with manufacturers for the purchase of generic drugs. The scope of these contracts varies from as few as one drug to as many as all the drugs a specific customer may buy from a specific manufacturer. The duration of these contracts also varies and may last for as long as a year or more. Customers typically enter into contracts with multiple manufacturers.
- 6. Customers often award contracts for particular generic drugs to manufacturers through a competitive bidding process. The bidding process may be limited to a particular drug or it may include multiple drugs. After receiving and evaluating the bids, customers generally award the contract at issue to the manufacturer offering the lowest price for each drug that they may need during the term of the contract. The contract may give the manufacturer the exclusive

right to supply that drug or may designate the winning manufacturer as the "preferred" provider or "supplier."

- 7. The contracts between customers and manufacturers of generic drugs set out numerous terms and conditions of sale. These terms include the price per unit that the manufacturer will charge, which is sometimes referred to as the contract price or the invoice price, and any discounts from that price, which include administrative fees, restocking fees, prompt payment discounts, and volume incentive rebates. The net price per unit, after all discounts are accounted for, is sometimes referred to in the generic drug industry as the "dead net" price.
- 8. Some manufacturers group the different types of customers into "classes of trade" and, in general, charge customers in one class of trade a different price from customers in another class of trade. There is no regulation that requires manufacturers to disclose or report the contract, invoice, or dead net prices they charge any particular customer or group of customers, and there is no public or commercial publication that regularly reports this data. As a result, neither a customer seeking to determine what another customer is paying for a particular drug, nor a manufacturer seeking to determine what another manufacturer is charging for a particular drug, can obtain that information from public or commercial sources.
- 9. Some manufacturers regularly seek to add to the number of generic drugs they offer to sell. They may do so by, among other things, introducing a new strength of an existing generic drug, introducing an existing generic drug in a new package or formulation, developing or obtaining the right to sell an existing generic drug that it had not previously sold, or reintroducing a generic drug that it had previously stopped selling. The addition of a generic

drug to a manufacturer's offerings is commonly referred to in the pharmaceutical industry as a "launch."

DEFENDANTS AND THEIR CO-CONSPIRATORS

- 10. Defendant **TEVA PHARMACEUTICALS USA, INC.** ("TEVA") was a corporation incorporated in Delaware with its principal place of business in Montgomery County, Pennsylvania, within the Eastern District of Pennsylvania. Defendant TEVA, directly and through related entities, was engaged in the manufacturing of generic drugs, and the marketing and sale of generic drugs in the United States.
- 11. Defendant **GLENMARK PHARMACEUTICALS INC., USA**("GLENMARK") was a corporation incorporated in Delaware with its principal place of business in Mahwah, New Jersey. Defendant GLENMARK marketed and sold generic drugs in the United States.
- 12. Apotex Corp. ("Apotex"), charged elsewhere, was a corporation incorporated in Delaware with its principal place of business in Florida. Apotex marketed and sold generic drugs in the United States.
- 13. Defendant TEVA, defendant GLENMARK, Apotex, and others known and unknown to the grand jury were competitors in the marketing and sale of generic drugs, including pravastatin, in the United States. Pravastatin was a generic drug used to lower cholesterol and thus reduce the risk of heart attack and stroke.
- 14. Cooperating witness 1 ("CW-1"), an individual known to the grand jury, was employed at defendant TEVA, first as a pricing executive and later as a sales executive.
- 15. Cooperating witness 2 ("CW-2"), an individual known to the grand jury, was employed at defendant GLENMARK as an executive involved in the pricing, sale, and

marketing of generic drugs.

- 16. Individual 1, an individual known to the grand jury, was employed at defendant TEVA as an executive involved in the pricing, sale, and marketing of generic drugs.
- 17. Individual 2, an individual known to the grand jury, was employed at Apotex as an executive involved in the pricing, sale, and marketing of generic drugs.
- 18. Various entities and individuals, not made defendants in this count, known and unknown to the grand jury, participated as co-conspirators in the offense charged herein and performed acts and made statements in furtherance thereof.
- 19. Any reference in this count to any act, deed, or transaction of any corporation means that the corporation engaged in the act, deed, or transaction by or through its officers, directors, employees, agents, or other representatives while they were actively engaged in the management, direction, control, or transaction of its business or affairs.

DESCRIPTION OF THE OFFENSE

20. Beginning in or around May 2013 and continuing until at least in or around December 2015, the exact dates being unknown to the grand jury, in the Eastern District of Pennsylvania and elsewhere, defendants

TEVA PHARMACEUTICALS USA, INC. and GLENMARK PHARMACEUTICALS INC., USA

and their co-conspirators, known and unknown to the grand jury, including Apotex, CW-1, CW-2, Individual 1, and Individual 2, knowingly entered into and engaged in a conspiracy to suppress and eliminate competition by agreeing to increase and maintain prices of pravastatin and other generic drugs sold in the United States. The conspiracy engaged in by the defendants and their co-conspirators was a *per se* unlawful, and thus unreasonable, restraint of interstate trade and commerce in violation of Section 1 of the Sherman Act (15 U.S.C. § 1).

MEANS AND METHODS

- 21. For the purpose of forming and carrying out the charged conspiracy, defendant TEVA, defendant GLENMARK, and their co-conspirators known and unknown to the grand jury did certain acts, including and among others:
 - (a) communicated about the sale of generic drugs in the United States;
 - (b) agreed during those communications to increase and maintain the prices of generic drugs sold by defendant TEVA, defendant GLENMARK, and Apotex in the United States;
 - exchanged during those communications non-public pricing information
 in order to accomplish the price increases for generic drugs;
 - (d) submitted price increase notifications to customers for generic drugs;
 - (e) refrained from submitting bids and offers for, submitted non-competitive bids and offers for, and declined requests to submit bids and offers for, the sale of generic drugs, to customers that previously purchased from a competing company;
 - (f) sold generic drugs to customers at collusive and noncompetitive prices;
 - (g) received payments for generic drugs sold at collusive and noncompetitive prices; and
 - (h) participated in communications for the purpose of reaffirming, monitoring, and enforcing adherence to the agreement.
- 22. For example, on or about May 2, 2013, CW-1 and CW-2 communicated by phone and discussed that defendant TEVA would follow a price increase by defendant GLENMARK on several generic drugs that defendant TEVA and defendant GLENMARK both sold, including

pravastatin.

- 23. On or about May 15, 2013, defendant GLENMARK distributed price increase notifications to its customers, announcing increases to the prices of certain generic drugs, including pravastatin, effective May 16, 2013.
- 24. In or around May 2013, CW-1 and Individual 2 communicated by phone and discussed that defendant TEVA and Apotex would increase prices on pravastatin.
- 25. In or around July 2013, defendant TEVA increased its prices for certain generic drugs that defendant TEVA and defendant GLENMARK both sold. On or about August 9, 2013, defendant TEVA increased its prices for pravastatin.
- 26. Between May 2013 and August 2013, CW-1 and others at defendant TEVA communicated with co-conspirators at defendant GLENMARK and other companies about the prices of generic drugs, including pravastatin, for the purpose of ensuring the success of the price increases.
- 27. On or about December 2, 2013, after a large customer moved its pravastatin business from defendant TEVA to defendant GLENMARK, Individual 1 at defendant TEVA contacted CW-2 at defendant GLENMARK by phone to complain that defendant GLENMARK had taken the customer from defendant TEVA.
- 28. Defendant TEVA, defendant GLENMARK, and Apotex continued to receive and accept payments for generic drugs affected by the conduct described in this count sold at collusive and noncompetitive prices until at least in or around December 2015.

TRADE AND COMMERCE

29. During the period covered by this count, defendant TEVA, defendant GLENMARK, and their co-conspirators, including Apotex, sold substantial quantities of

generic drugs affected by the offense charged in this count to customers located in various states in the United States. In addition, payments from affected customers that purchased drugs sold by defendant TEVA and defendant GLENMARK and their co-conspirators, including Apotex, traveled in interstate trade and commerce.

30. During the period covered by this count, the activities of defendant TEVA, defendant GLENMARK and their co-conspirators, including Apotex, with respect to the sale of affected generic drugs were within the flow of, and substantially affected, interstate trade and commerce.

All in violation of Title 15, United States Code, Section 1.

GAIN AND LOSS

31. With respect to the offense charged in Count One of this Indictment, for purposes of determining the alternative maximum fine pursuant to Title 18, United States Code, Section 3571(d), defendant TEVA, defendant GLENMARK and their co-conspirators known and unknown to the grand jury derived gross gains of at least \$200,000,000, and persons other than the defendants and their co-conspirators suffered gross losses of at least \$200,000,000.

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COUNT TWO CONSPIRACY TO RESTRAIN TRADE (15 U.S.C. § 1)

THE GRAND JURY FURTHER CHARGES THAT:

At all times relevant to this count:

32. Paragraphs 1-10, 14, and 18-19 of Count One are repeated, realleged, and incorporated in Count Two as if fully set forth in this Count.

DEFENDANT TEVA'S CO-CONSPIRATORS

- 33. Taro Pharmaceuticals U.S.A., Inc. ("Taro U.S.A."), charged elsewhere, was a corporation organized and existing under the laws of New York, with its principal place of business in Hawthorne, New York. Taro U.S.A. was a pharmaceutical company engaged, directly or through related entities, in the manufacturing of generic drugs, and the marketing and sale of generic drugs in the United States.
- 34. Ara Aprahamian ("Aprahamian"), charged elsewhere, was the Vice President of Rx Marketing at Taro U.S.A. from in or around March 2013 until in or around April 2014, and the Vice President of Sales and Marketing at Taro U.S.A. from in or around April 2014 until at least in or around December 2015. Aprahamian was responsible for overseeing generic drug sales, pricing, and contracts at Taro U.S.A.
- 35. Defendant TEVA and Taro U.S.A. were competitors in the marketing and sale of generic drugs in the United States.

DESCRIPTION OF THE OFFENSE

36. From at least as early as May 2013 and continuing until at least in or around December 2015, the exact dates being unknown to the grand jury, in the Eastern District of Pennsylvania and elsewhere, defendant

TEVA PHARMACEUTICALS USA, INC.

and its co-conspirators, known and unknown to the grand jury, including CW-1, Taro U.S.A., and Aprahamian, knowingly entered into and engaged in a conspiracy to suppress and eliminate competition by agreeing to allocate customers and rig bids for, and stabilize, maintain, and fix prices of, generic drugs sold in the United States. The conspiracy engaged in by defendant TEVA and its co-conspirators was a *per se* unlawful, and thus unreasonable, restraint of interstate trade and commerce in violation of Section 1 of the Sherman Act (15 U.S.C. § 1).

MEANS AND METHODS

- 37. For the purpose of forming and carrying out the charged conspiracy, defendant TEVA and its co-conspirators known and unknown to the grand jury did certain acts, including and among others:
 - (a) discussed and agreed to increase prices for generic drugs;
 - (b) communicated about the timing of anticipated price increases;
 - (c) provided and received specific non-public prices in connection with agreed-upon price increases;
 - (d) negotiated the amount of agreed-upon price increases;
 - (e) implemented price increases in accordance with the agreement reached;
 - (f) declined requests to submit bids and offers from customers in accordance with the agreement reached; and
 - (g) sold and accepted payment for generic drugs at collusive and noncompetitive prices.
- 38. On numerous occasions, defendant TEVA and Taro U.S.A. discussed and agreed to increase prices on certain generic drugs generally in the following manner: CW-1 and

Aprahamian discussed the amount of a potential price increase and encouraged the other to follow. If defendant TEVA was leading the price increase, CW-1 provided Aprahamian with some of defendant TEVA's new, non-public prices, and if Taro U.S.A. was leading the price increase, Aprahamian provided CW-1 with some of Taro U.S.A.'s new, non-public prices. CW-1 and Aprahamian then used these non-public prices to implement price increases at defendant TEVA and Taro U.S.A. The purpose of the communications between CW-1 and Aprahamian was to ensure that the new, higher prices were implemented and maintained, as much as possible, at the level discussed, and to limit the ability of defendant TEVA and Taro U.S.A.'s customers to switch suppliers.

39. The conversations about price increases occurred with respect to the following generic drugs, among others: carbamazepine tabs and chews, medications used to prevent and control seizures and treat bipolar disorder; clotrimazole topical solution 1%, a medication used to treat a variety of skin conditions; etodolac immediate release ("IR") and extended release ("ER") tablets, medications used to treat pain and arthritis; fluocinonide cream, emollient cream, gel, and ointment, medications used to treat skin conditions; and warfarin, a medication used to treat and prevent blood clots.

40. For example, in or around July and August 2013, CW-1, acting on behalf of defendant TEVA, and Aprahamian, acting on behalf of Taro U.S.A., discussed and agreed to increase prices for etodolac ER. Defendant TEVA and Taro U.S.A. were the only two suppliers of etodolac ER at this time. During numerous calls, CW-1 and Aprahamian identified and discussed specific non-public prices for etodolac ER, and agreed to specific new, higher WAC and other prices for three sizes of etodolac ER. Approximately six days before either defendant TEVA or Taro U.S.A. announced a price increase for etodolac ER to their customers or

commercial publications, CW-1 and Aprahamian each circulated spreadsheets within their respective companies containing the specific agreed-upon proposed WAC and other prices for etodolac ER. After being told by CW-1 that defendant TEVA was going to implement the agreed-upon etodolac ER price increase on or about August 9, 2013, Aprahamian ensured that Taro U.S.A. implemented its etodolac ER increase on the same date.

41. Defendant TEVA and Taro U.S.A. continued to receive and accept payments for generic drugs affected by the conduct described in this count sold at collusive and noncompetitive prices until at least in or around December 2015.

TRADE AND COMMERCE

- 42. During the period covered by this count, defendant TEVA and Taro U.S.A. sold substantial quantities of generic drugs affected by the offense charged in this count to customers located in various states in the United States. In addition, payments from affected customers that purchased drugs sold by defendant TEVA and Taro U.S.A. traveled in interstate trade and commerce.
- 43. During the period covered by this count, the activities of defendant TEVA and its co-conspirators, including Taro U.S.A., with respect to the sale of affected generic drugs were within the flow of, and substantially affected, interstate trade and commerce.

All in violation of Title 15, United States Code, Section 1.

GAIN AND LOSS

With respect to the offense charged in Count Two of this Indictment, for purposes of determining the alternative maximum fine pursuant to Title 18, United States Code, Section 3571(d), defendant TEVA and its co-conspirators known and unknown to the grand jury derived

gross gains of at least \$75,000,000 and persons other than defendant TEVA and its coconspirators suffered gross losses of at least \$75,000,000.

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COUNT THREE CONSPIRACY TO RESTRAIN TRADE (15 U.S.C. § 1)

THE GRAND JURY FURTHER CHARGES THAT:

At all times relevant to this count:

44. Paragraphs 1-10, 14, and 18-19 of Count One are repeated, realleged, and incorporated in Count Three as if fully set forth in this Count.

DEFENDANT TEVA'S CO-CONSPIRATORS

- 45. Sandoz Inc. ("Sandoz"), charged elsewhere, was a corporation organized and existing under the laws of Colorado, with its principal place of business in Princeton, New Jersey. Sandoz, directly or through related entities, was engaged in the manufacturing of generic drugs, and the marketing and sale of generic drugs in the United States.
- 46. Defendant TEVA and Sandoz were competitors in the marketing and sale of generic drugs in the United States.
- 47. Cooperating witness 3 ("CW-3"), an individual known to the grand jury, was employed at Sandoz as a pricing and contracts executive.

DESCRIPTION OF THE OFFENSE

48. From at least as early as May 2013 and continuing until at least in or around December 2015, the exact dates being unknown to the grand jury, in the Eastern District of Pennsylvania and elsewhere, defendant

TEVA PHARMACEUTICALS USA, INC.

and its co-conspirators, known and unknown to the grand jury, including CW-1, Sandoz, and CW-3, knowingly entered into and engaged in a conspiracy to suppress and eliminate competition by agreeing to allocate customers and rig bids for, and to stabilize, maintain, and fix

prices of, generic drugs sold in the United States. The conspiracy engaged in by defendant TEVA and its co-conspirators was a *per se* unlawful, and thus unreasonable, restraint of interstate trade and commerce in violation of Section 1 of the Sherman Act (15 U.S.C. § 1).

MEANS AND METHODS

- 49. For the purpose of forming and carrying out the charged conspiracy, defendant TEVA and its co-conspirators known and unknown to the grand jury did certain acts, including and among others:
 - (a) discussed and agreed to increase prices for generic drugs;
 - (b) communicated about the timing of anticipated price increases;
 - (c) provided and received specific non-public prices in connection with agreed-upon price increases;
 - (d) implemented price increases in accordance with the agreement reached;
 - (e) discussed the allocation of and agreed to allocate customers located in the United States;
 - (f) submitted bids and offers to, and declined requests to submit bids and offers from, customers in accordance with the agreement reached; and
 - (g) sold and accepted payment for generic drugs at collusive and noncompetitive prices.
- 50. With respect to certain generic drugs, when defendant TEVA or Sandoz were preparing to launch a generic drug sold by the other company, CW-1, acting on behalf of defendant TEVA, and CW-3, acting on behalf of Sandoz, discussed what share of the market the launching company wanted to obtain. They also discussed customers the launching company might solicit and customers the current supplier was willing to relinquish. During those

conversations, or shortly thereafter, defendant TEVA and Sandoz, through their employees, reached an agreement on which customers the launching company would solicit. The purpose of the conversations between CW-1, acting on behalf of defendant TEVA, and CW-3, acting on behalf of Sandoz, with respect to launches was to allow the launching company to obtain customers quickly at the highest price possible, and minimize the decline of price for drugs being launched.

- 51. For example, beginning in or around July 2014, CW-1 discussed Sandoz's launch of tobramycin inhalation solution ("tobramycin") with CW-3. At the time of Sandoz's launch, defendant TEVA was the exclusive supplier of tobramycin. CW-1 and CW-3 discussed which customers defendant TEVA wanted to retain, and which customers Sandoz should pursue. CW-1, acting on behalf of defendant TEVA, agreed to relinquish a large national retail chain customer to Sandoz. After the customer asked defendant TEVA for its best and final offer to retain the business, defendant TEVA declined to bid or compete to retain the customer.
- 52. On other occasions, when defendant TEVA or Sandoz was planning to raise its WAC prices or had recently done so, CW-1 and CW-3 discussed the amount of a potential price increase, provided the other with non-public prices, and encouraged the other to also raise prices. After the discussions, defendant TEVA and Sandoz usually followed the other company's price increase and declined to pursue the other company's customers. The purpose of the communications between CW-1 and CW-3 was to ensure that the new, higher prices were implemented and maintained, as much as possible, at the level discussed, and to limit the ability of defendant TEVA's and Sandoz's customers to switch suppliers.
- 53. The conversations about price increases and launches occurred with respect to the following drugs, among others: etodolac immediate release tablets, a medication used to treat

pain and arthritis; nadolol, a beta-blocker used to treat high blood pressure and prevent chest pain; temozolomide, a chemotherapy drug used to treat brain cancer; and tobramycin, an antibiotic used in the treatment of cystic fibrosis.

54. Defendant TEVA and Sandoz continued to receive and accept payments for generic drugs affected by the conduct described in this count sold at collusive and noncompetitive prices until at least in or around December 2015.

TRADE AND COMMERCE

55. During the period covered by this count, defendant TEVA and Sandoz sold substantial quantities of generic drugs affected by the offense charged in this count to customers located in various states in the United States. In addition, payments from affected customers that purchased drugs sold by defendant TEVA and Sandoz traveled in interstate trade and commerce.

56. During the period covered by this count, the activities of defendant TEVA and its co-conspirators, including Sandoz, with respect to the sale of affected generic drugs were within the flow of, and substantially affected, interstate trade and commerce.

All in violation of Title 15, United States Code, Section 1.

GAIN AND LOSS

57. With respect to the offense charged in Count Three of this Indictment, for purposes of determining the alternative maximum fine pursuant to Title 18, United States Code, Section 3571(d), defendant TEVA and its co-conspirators known and unknown to the grand jury derived gross gains of at least \$75,000,000 and persons other than defendant TEVA and its co-conspirators suffered gross losses of at least \$75,000,000.



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UNITED STATES DISTRICT COURT

Eastern District of Pennsylvania

Criminal Division

THE UNITED STATES OF AMERICA

AND GLENMARK PHARMACEUTICALS INC., USA TEVA PHARMACEUTICALS USA, INC.

VS.

SECOND SUPERSEDING INDICTMENT

Counts

15 U.S.C. § 1 (conspiracy to restrain trade - 3 counts)

A true bill.	

Filed in open court this Of Clerk A.D. 20

day,

Bail, \$